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Sexual activity and function in women more than 2 years after midurethral sling placement

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Abstract

OBJECTIVE—The purpose of this study was to assess prospectively the effects of midurethral sling surgery on sexual function and activity.

STUDY DESIGN—Sexual activity and function was assessed in 597 women with stress urinary incontinence who were enrolled in a randomized equivalence trial of retropubic compared with transobturator midurethral slings. Repeated measures analysis of variance was used to assess changes in Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire scores over a 2-year period.

RESULTS—Significant, similar improvements in sexual function were seen in both midurethral sling groups. Mean Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire scores increased from 32.8 at baseline to 37.6 at 6 months and 37.3 at 24 months ($P < .0001$). Dyspareunia, incontinence during sex, and fear of incontinence during sex each significantly improved after surgery. Preoperative urge incontinence was associated with abstinence after surgery ($P = .02$); postoperative urge incontinence negatively impacted sexual function ($P = .047$).

CONCLUSION—Midurethral sling surgery for stress urinary incontinence significantly improves sexual function, although coexistent urge incontinence has a negative impact.

Keywords

mesh; midurethral sling; sexual function; surgery; urinary incontinence

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Urinary incontinence (UI) is estimated to affect approximately 40% of adult women.[1] Women with UI report decreased sexual activity and worse sexual function as a result of a loss of urine with sexual activity, embarrassment, and fear of leakage.[2,3] Importantly, incontinence-related sexual dysfunction negatively impacts overall quality of life in sexually active women.[4] Although stress UI (SUI) surgery is thought to improve sexual function,[5,6] complications of synthetic mesh midurethral slings (MUS), which include de novo or exacerbated voiding dysfunction, mesh exposure, and paraurethral banding, may each adversely affect postoperative sexual function.[7,8] Moreover, it is not known whether differences in the path of extrapelvic mesh between the sling routes or the extent of mesh within the anterior vaginal wall may affect sexual function. We performed a planned secondary analysis of women who were enrolled in the Trial of Midurethral Slings (TOMUS) study to assess prospectively the overall impact of MUS on sexual function over a period of 2 years after surgery and to identify factors that are associated with change in sexual function.

Materials and Methods

TOMUS was a multicenter, randomized equivalence trial in which women (n = 597) with stress predominant UI were assigned randomly at the time of surgery to either a retropubic or transobturator MUS. Eligible participants reported symptoms of either pure or predominant SUI for at least 3 months and demonstrated a positive standardized stress test. Key elements of the surgical procedures that included cystoscopy were standardized. Concomitant vaginal procedures were permitted; however, surgery could not include the use of any synthetic graft or anterior compartment biologic graft. All sites obtained local institutional review board approval, and participants provided written informed consent. A detailed description of the TOMUS trial and the primary results have been published previously.[9,10]

Information was obtained from clinical examinations, patient interviews, and self-administered questionnaires before surgery and at in-person postoperative visits that were conducted at 2 and 6 weeks and at 6, 12, and 24 months. Sexual function was assessed with the Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). The PISQ-12 is a condition-specific, validated, and reliable instrument that was designed to evaluate sexual function in women with UI and/or pelvic organ prolapse. This tool is able to distinguish women with poor sexual function as measured on the Sexual History Form -12. The PISQ-12 provides a single sexual function score that incorporates behavioral-emotive factors, physical factors, and partner-related factors. The maximum total score is 48; higher scores represent better sexual function.[11] Because of protocol-recommended limitations on intravaginal sexual activity during the first 6 weeks after surgery, the PISQ-12 was first administered after surgery at the 6-month visit. We also calculated the proportion of enrolled women who reported that they were sexually active at baseline and at 6, 12, and 24 months after surgery.

Overall surgical failure was defined by the occurrence of any of the following objective outcomes: a positive stress test, positive 24-hour pad test, or any type of retreatment for SUI. Self-reported urge-type UI was quantified with the Medical, Epidemiologic, and Social Aspects of Aging Project questionnaire. An index score was calculated from responses to questions that refer to urine loss preceded by an urge to void or uncontrollable voiding with little or no warning. The urge index has a response range from 0 (no urge symptoms) to 100 (all symptoms reported “often”).

For evaluation of changes over time after surgery in mean sexual function score and proportion of women who were sexually active, we used repeated measures analytic

methods to control for baseline values, assigned surgery, and failure status. For PISQ-12 scores, we used repeated measures analysis of covariance; for proportion of sexually active women, we used repeated measures logistic regression analysis. To evaluate the impact of urge incontinence on sexual function, a similar analysis was performed; we added urge index at each time point as a covariate in the repeated measures models described earlier.

Three items for the PISQ-12 were evaluated individually: pain during sexual activity (dyspareunia), incontinence during sexual activities, and fear of incontinence during sexual activities. The frequencies of affirmative responses to these items were calculated at baseline and at the 3 postoperative time points. To test the significance of change for these items, baseline and 12-month data were used. The 12-month dataset was selected because we demonstrated a sustained treatment effect through 24 months, and the 12-month sample was larger. We cross tabulated the baseline and 12-month reports of each symptom and tested for differences using a test of symmetry.

The minimum important difference (MID) is the change in a questionnaire score that represents the smallest magnitude of clinically significant improvement. An anchor-based MID for the PISQ-12 has not been published. An alternative method of the determination of a MID relies on the distribution of scores within or between groups and estimates a clinically significant change with the use of a statistical parameter such as variability (ie, SD).[12] This distribution-based MID designates a change of 0.5 SD as a “medium” effect size.[13]

Results

Study participants were predominantly white (79.2%), middle-aged (mean age, 52.9 ± 11.0 years), and overweight (body mass index, 30.3 ± 6.7 kg/m^2). The mean urge index at baseline was 35 ± 22. Baseline clinical characteristics and selected postoperative outcomes through 24 months by randomized surgery are shown in Table 1. Approximately two-thirds of the women (406 of 597 women; 68.1%) were sexually active at baseline.

Significant and similar improvements in sexual function over time were seen in both MUS groups; the mean PISQ-12 scores of the combined study population increased from 32.8 ± 7.1 at baseline to 37.6 ± 5.5 and 37.3 ± 6.0 at 6 months and 24 months, respectively ($P < .0001$). These changes are >0.6 SD units, which reflects “medium” improvement in the PISQ-12 score after surgery. Repeated measures analysis of variance of PISQ-12 scores after surgery, when controlled for baseline PISQ-12 score, found the improvement in sexual function was sustained over time with no differences identified between assigned type of surgery ($P = .44$; Figure 1). There was, however, a significant association between PISQ score and failure status. Compared with women with successful surgery, women who experienced surgical failure, regardless of assigned type of surgery, reported worse adjusted sexual function scores at all postoperative time points ($P = .009$; Table 2). Neither concomitant surgery nor baseline stage of prolapse was associated with postsurgery PISQ-12 scores.

The proportion of women who were sexually active after surgery was 67.2% at 6 months and 64.1% at 24 months. The data in Table 3 and Figure 2 show greater detail of the counts and percentages of women who were sexually active in the preceding 6 months by assigned type of surgery. The proportion of sexually active women did not differ significantly from baseline ($P = .69$) and did not vary significantly over the 2 years after surgery ($P = .31$). Sexual activity was not associated significantly with treatment assignment ($P = .58$), failure status ($P = .26$), concomitant surgery ($P = .19$), or baseline stage of prolapse ($P = .06$). Neither intraoperative nor postoperative complications were associated significantly with

sexual activity or function. When sexual activity was analyzed with "last observation carried forward" in women who completed the baseline PISQ-12 but were found to have missing data at subsequent time points, the results were unchanged.

To determine the impact of urge incontinence on sexual activity and function, we used repeated measures analysis and controlled for baseline activity or function, baseline urge index, treatment group, and failure status. Preoperative urge index was associated significantly with postsurgery sexual activity ($P = .02$). Greater severity of urge incontinence before surgery was associated with lower odds of being sexually active after surgery, even after we controlled for age. Additionally, severity of postoperative urge incontinence was associated significantly with diminished sexual function as measured by PISQ-12 ($P = .047$) but did not impact on the frequency of self-reported sexual activity.

Improvement in PISQ-12 scores was consistent with change in the 3 specific items from the sexual function measure of interest: (1) the experience of pain during sexual activity, (2) UI during sexual activity, and (3) fear of incontinence during sexual activities. The first 2 items were asked only of women who reported being sexually active with a partner in the preceding 6 months. The third item was asked of all women.

Pain with intercourse was reported by 153 of 406 of sexually active women (38%) at baseline and decreased to 27% at 12 months after surgery ($P = .003$). Self-reported UI and the fear of incontinence occurring during sexual activity also significantly improved by 12 months after surgery, regardless of sling route ($P < .0001$ for both). Figure 3 shows changes from baseline to 12 months after surgery of these 3 negative experiences during sexual activity. To specifically investigate the association of synthetic mesh slings on dyspareunia, we repeated the analysis on the 247 women who underwent MUS only (no concurrent procedures) and who completed baseline and 12-month assessments. In this subset of women, dyspareunia decreased from 57% at baseline to 43% at 12 months after surgery ($P = .03$).

Comment

Among sexually active women who had an MUS placed (retropubic or transobturator), sexual function as reported on the PISQ-12 improved significantly over the first 2 years after surgery without notable differences between the 2 studied techniques. Although improvement was statistically greater in women with surgical success, this difference was not clinically important.

Importantly, we did not detect any decrease in the proportion of women who reported sexual activity during these 2 years, and sexually active women reported less dyspareunia. Before surgery, 40% of sexually active women reported pain during sexual activity. The cause of dyspareunia is often multifactorial. MUS surgery has the potential to initiate or exacerbate dyspareunia. Fortunately, neither MUS studied in this trial was associated with an increase of pain during sexual activity. The reason for our finding of pain improvement is unclear but may also be multifactorial. It is plausible that our finding of decreased fear of UI during sexual activity may be responsible for some additional comfort and confidence during intimacy.

Successful surgical treatment of SUI by retropubic or transobturator MUS promotes improvement in these important patient symptoms. Thus, sexually active women who undergo MUS to treat SUI can anticipate enhanced sexual function. However, the presence or fear of any form of UI during sexual activity can undermine intimacy seriously. This may explain our observation that increasing severity of postoperative urgency incontinence is associated with poorer sexual function during follow-up evaluation. This finding also

reinforces the negative effect of persistent and/or de novo urgency incontinence on patient satisfaction with their antiincontinence procedure.[14] Additionally, we found that greater severity of preoperative urge incontinence is associated with lower odds of being sexually active after surgery. In fact, women with UI report several factors that contribute to abstinence: loss of spontaneity, the need for separate beds, a general feeling of unattractiveness, and concerns of odor.[15] Urgency incontinence is known to worsen overall preoperative symptom severity,[16] to impact postoperative patient satisfaction and goal achievement,[14] and to be associated with postoperative incontinence.[17] Surgeons are well-aware of the difficulties in planning treatment for women who experience both bothersome stress incontinence and urge incontinence, and our findings can enhance surgical counseling.

Postoperative urgency incontinence reduced, but did not negate, the sexual function improvement after MUS. Sexual function is influenced most certainly by both psychologic and biologic processes; it is intriguing to consider the role of surgery on psychologic well-being. It is likely that there are important factors beyond those in the PISQ-12 that affect sexual well-being, including body image, optimism, and self-confidence. In addition, the perspective of the patient's sexual partner may change. Little is known about the male partner's perspective of women who undergo SUI surgery or the effect of changing partner attitudes on affected women. However, 1 study has shown that male partners of women with UI have diminished sexual function, lower frequency of intercourse, less sexual satisfaction, and more erectile dysfunction than men with continent partners.[18]

The findings from this trial are consistent with other surgical treatment trials for SUI. Participants in the Stress Incontinence Surgical Treatment Efficacy (SISTEr) trial, which compared the fascial sling and Burch urethropexy, also reported improvements in sexual function with a statistically and clinically significant reduction in the proportion of women who experienced pain during sexual activity.[5] In the TOMUS trial, we did not detect an effect from route of MUS insertion; this may be related to the high rates of surgical success with both retropubic and transobturator approaches. Reassuringly, we did not identify any sustained deleterious impact of intra- or perioperative complications on sexual activity or function by the 6-month visit.

Any study of sexual function is subject to limitations, because the topic is highly personal and may be difficult for patients to discuss. The use of a validated questionnaire allows comparisons with other treated populations. However, this questionnaire does not have a published anchor-based MID to validate what we believe to be clinically meaningful improvements in sexual function scores, nor does it include open-ended questions that might allow our participants to further describe their sexual function. The strengths of this study include the large number of affected women who were well-characterized with regard to continence status and who reported both baseline and postoperative sexual function. Nonetheless, our understanding of a woman's expectations and goals for sexual function are understood incompletely. Further research should focus on both patient and sexual partner fears, expectations, and goals regarding perioperative changes in sexual function.

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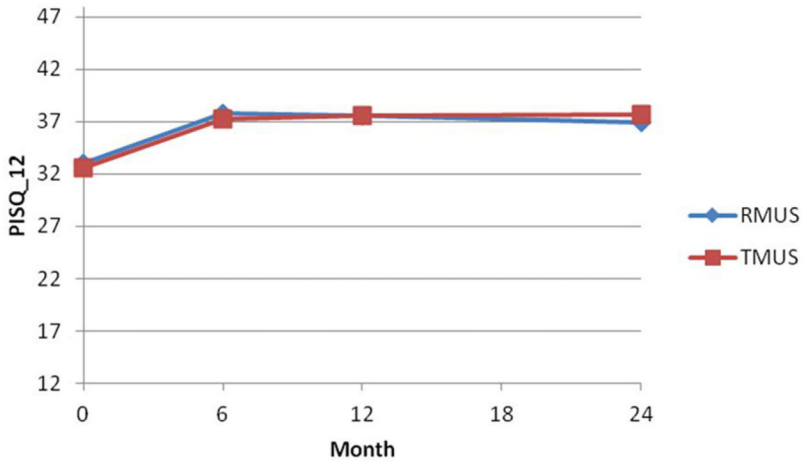

FIGURE 1. Mean PISQ-12 score by assigned surgery at baseline and 6, 12, and 24 months after surgery

PISQ-12, Prolapse/Urinary Incontinence Sexual Questionnaire; *RMUS*, retropubic midurethral sling; *TMUS*, transobturator midurethral sling.

Zyczynski. Sexual function after midurethral slings. Am J Obstet Gynecol 2012.

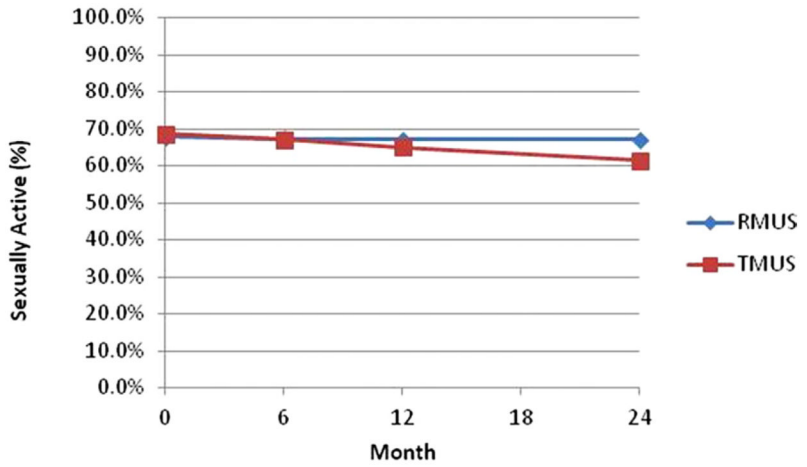

FIGURE 2. Proportion of women sexually active by assigned surgery at baseline and during follow-up

RMUS, retropubic midurethral sling; *TMUS*, transobturator midurethral sling.

Zyczynski. Sexual function after midurethral slings. Am J Obstet Gynecol 2012.

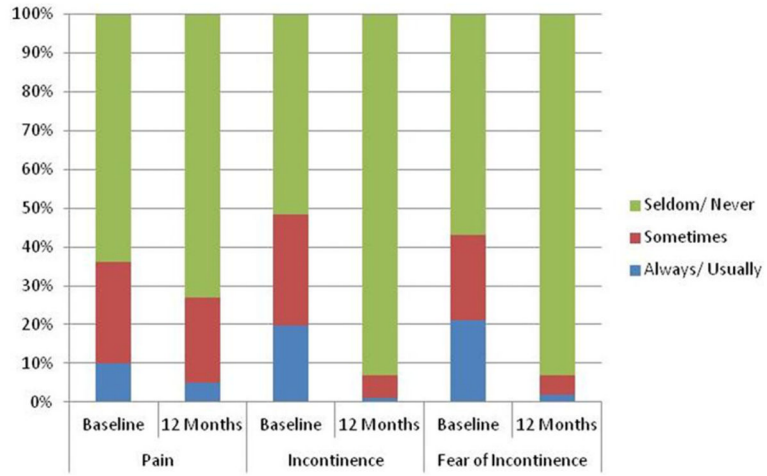

FIGURE 3. Reported negative experiences during sexual activity at baseline and after midurethral sling surgery

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TABLE 1

Baseline characteristics and surgical outcomes overall and by assigned surgery

Variable	Treatment		Total (n = 597)
	Transobturator midurethral sling (n = 299)	Retropubic midurethral sling (n = 298)	
Baseline			
Age, y[a]	53.1 ± 11.5	52.7 ± 10.5	52.9 ± 11.0
Ethnic origin, n (%)			
Hispanic	38 (12.7)	33 (11.1)	71 (11.9)
Non-Hispanic white	233 (77.9)	240 (80.5)	473 (79.2)
Other	28 (9.4)	25 (8.4)	53 (8.9)
Body mass index, kg/m^2[a]	30.0 ± 6.5	30.6 ± 7.0	30.3 ± 6.7
Socioeconomic status score[a,b]	59.6 ± 22.7	59.2 ± 23.0	59.4 ± 22.8
Menopausal, n (%)	206 (69.1)	209 (70.4)	415 (69.7)
Hormone therapy: systemic, n (%)	90 (30.2)	81 (27.3)	171 (28.7)
Abstinence, n (%)	94 (31.5)	96 (32.2)	190 (31.9)
Severity of urge incontinence[a,c]	36.5 ± 22.0	33.0 ± 22.0	34.8 ± 22.1
Prolapse/Urinary Incontinence Sexual Questionnaire score[a]	32.6 ± 7.1	33.0 ± 7.1	32.8 ± 7.1
INTRAOPERATIVE AND POSTOPERATIVE OUTCOME			
Trocar perforation, n (%)			
Bladder/urethra	0	16 (5.4)	16 (2.7)
Vaginal	13 (4.3)	6 (2.0)	19 (3.2)
Voiding dysfunction, n (%)			
Managed with surgery	0	8 (3.3)	8 (1.6)
Managed with catheter reinsertion	7 (2.8)	13 (5.4)	20 (4.1)
Managed with medication/other	1 (0.4)	1 (0.4)	2 (0.4)
Mesh exposure adverse event, n (%)	8 (2.7)	13 (4.4)	21 (3.5)
Reoperation, n (%)[d]	80 (26.8)	66 (22.1)	146 (24.5)
Overall surgical failure, n (%)	165 (61.1)	139 (53.9)	304 (57.6)
Any neurologic adverse event, n (%)	29 (9.7)	16 (5.4)	45 (7.5)

[a] Data are given as mean ± SD;

[b] Nam-Powers-Boyd Occupational Status Score (range, 1–100);

[c] Medical, Epidemiologic, and Social Aspects of Aging Project Urge Index;

[d] Indications for reoperation included mesh erosion or exposure, voiding dysfunction, and retreatment of stress incontinence.

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TABLE 2

Sexual function scores by surgical success after midurethral sling surgery

	Adjusted mean PISQ-12 Score[a] (±SE)			
	Retropubic midurethral sling		Transobturator midurethral sling	
Months	Success	Failure	Success	Failure
6	37.4 (0.44)	36.7 (0.74)	37.4 (0.44)	36.3 (0.67)
12	37.0 (0.46)	36.0 (0.57)	37.3 (0.47)	36.4 (0.58)
24	36.9 (0.54)	35.9 (0.51)	37.3 (0.54)	36.9 (0.52)

PISQ, Prolapse/Urinary Incontinence Sexual Questionnaire.

[a]Controlled for baseline PISQ-12 score, concomitant surgery, and baseline stage of prolapse.

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TABLE 3

Sexual activity change overtime after midurethral sling surgery

		Reported sexual activity in the preceding 6 mo after surgery[a]					
		At 6 mo		At 12 mo		At 24 mo	
Variable	**Total**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**
Baseline, n							
No	190	146	24	150	20	129	21
Yes	406	27	330	29	326	38	279
Complete cases[b]							
Sexually active, %	68.1		67.2		65.9		64.2
Sexual activity by treatment group, %							
Retropubic midurethral sling	67.8		67.3		67.0		67.0
Transobturator midurethral sling	68.5		67.0		65.0		61.4

[a] Numbers do not sum to baseline totals because of missing values;

[b] Those cases with Prolapse/Urinary Incontinence Sexual Questionnaire results at baseline and at a designated postoperative time point.

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